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Attorney Docket No.: 023070-13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michael German et al.

Application No.: 09/811,323

Filed: March 16, 2001

For: DELIVERY OF THERAPEUTIC

GENE PRODUCTS BY

INTESTINAL CELL EXPRESSION

Examiner:

Dave Trong Nguyen

Art Unit:

1632

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

We, Michael S. German, Associate Professor of Medicine at the University of California, San Francisco (UCSF); Stephen Rothman, Professor of Stomatology and Physiology at UCSF; and Ira D. Goldfine, Professor in Residence of Medicine and Physiology at UCSF, state as follows:

- 1. We are co-inventors of the invention claimed in U.S. Patent Application No. 09/811,323, filed March 16, 2001 (herein "the '323 Application"), which claims priority to U.S. Patent Application No. 08/717,084, filed September 20, 1996.
- 2. The invention disclosed and claimed in the '323 Application is directed to, inter alia, methods of delivering a secreted protein to the bloodstream by intestinal cell expression of a foreign gene encoding the protein. In one embodiment of our invention, the method comprises the following steps: